APPLICATION OF ELECTROCHEMICAL IMPEDANCE SPECTROSCOPY IN SENSOR SYSTEMS, DEVICES, AND RELATED METHODS

RELATED APPLICATION DATA

This application claims the benefit of U.S. Provisional Application Ser. No. 61/755,811, filed Jan. 23, 2013, and of U.S. Provisional Application Ser. No. 61/754,475, filed Jan. 18, 2013, and of U.S. Provisional Application Ser. No. 61/754,479, filed Jan. 18, 2013, and of U.S. Provisional Application Ser. No. 61/754,483, filed Jan. 18, 2013, and of U.S. Provisional Application Ser. No. 61/754,485, filed Jan. 18, 2013, and of U.S. Provisional Application Ser. No. 61/657,517, filed Jun. 8, 2012, all of which are incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

Embodiments of this invention are related generally to methods and systems of using Electrochemical Impedance Spectroscopy (EIS) in conjunction with continuous glucose monitors and, more particularly, to the use of EIS in sensor diagnostics and fault detection, sensor calibration, sensor-signal optimization via one or more fusion algorithms, contaminant/interferent detection, and electrode-surface characterization, as well as to Application Specific Integrated Circuits (ASICs) for implementing such use of EIS for both single-electrode and multi-electrode (redundant) sensors.

BACKGROUND OF THE INVENTION

Subjects and medical personnel wish to monitor readings of physiological conditions within the subject's body. Illustratively, subjects wish to monitor blood glucose levels in a subject's body on a continuing basis. Presently, a patient can measure his/her blood glucose (BG) using a BG measurement device (i.e. glucose meter), such as a test strip meter, a continuous glucose measurement system (or a continuous glucose monitor), or a hospital hemacue. BG measurement devices use various methods to measure the BG level of a patient, such as a sample of the patient's blood, a sensor in contact with a bodily fluid, an optical sensor, an enzymatic sensor, or a fluorescent sensor. When the BG measurement device has generated a BG measurement, the measurement is displayed on the BG measurement device.

Current continuous glucose measurement systems include subcutaneous (or short-term) sensors and implantable (or long-term) sensors. For each of the short-term sensors and the long-term sensors, a patient has to wait a certain amount of time in order for the continuous glucose sensor to stabilize and to provide accurate readings. In many continuous glucose sensors, the subject must wait three hours for the continuous glucose sensor to stabilize before any glucose measurements are utilized. This is an inconvenience for the patient and in some cases may cause the patient not to utilize a continuous glucose measurement system.

Further, when a glucose sensor is first inserted into a patient's skin or subcutaneous layer, the glucose sensor does not operate in a stable state. The electrical readings from the sensor, which represent the glucose level of the patient, vary over a wide range of readings. In the past, sensor stabilization used to take several hours. A technique for sensor stabilization is detailed in U.S. Pat. No. 6,809,653, ("the '653 patent"), application Ser. No. 09/465,715, filed Dec. 19, 1999, issued Oct. 26, 2004, to Mann et al., assigned to Medtronic Minimed, Inc., which is incorporated herein by reference. In the '653 patent, the initialization process for sensor stabilization may be reduced to approximately one hour. A high voltage (e.g., 1.0-1.2 volts) may be applied for 1 to 2 minutes to allow the sensor to stabilize and then a low voltage (e.g., between 0.5-0.6 volts) may be applied for the remainder of the initialization process (e.g., 58 minutes or so). Thus, even with this procedure, sensor stabilization still requires a large amount of time.

It is also desirable to allow electrodes of the sensor to be sufficiently "wetted" or hydrated before utilization of the electrodes of the sensor. If the electrodes of the sensor are not sufficiently hydrated, the result may be inaccurate readings of the patient's physiological condition. A user of current blood glucose sensors is instructed to not power up the sensors immediately. If they are utilized too early, current blood glucose sensors do not operate in an optimal or efficient fashion. No automatic procedure or measuring technique is utilized to determine when to power on the sensor. This manual process is inconvenient and places too much responsibility on the patient, who may forget to apply or turn on the power source.

Besides the stabilization and wetting problems during the initial stages of sensor life, there can be additional issues during the sensor's life. For instance, all sensors are pre-set with a specified operating life. For example, in current short-term sensors on the market today, the sensors are typically good for 3 to 5 days. Although sensors may continue to function and deliver a signal after the pre-set operating life of the sensor, the sensor readings eventually become less consistent and thus less reliable after the pre-set operating life of the sensor has passed. The exact sensor life of each individual sensor varies from sensor to sensor, but all sensors have been approved for at least the pre-set operating life of the sensor. Therefore, manufacturers have required the users of the sensors to replace the sensors after the pre-set operating life has passed. Although the continuous glucose measurement system can monitor the length of time since the sensor was inserted and indicate the end of the operating life of a sensor to warn the user to replace the sensor, it does not have enough safeguards to prevent the sensor from being used beyond the operating life. Even though the characteristic monitors can simply stop functioning once the operating life of the sensor is reached, a patient may bypass these safeguards by simply disconnecting and re-connecting the same sensor. Thus, there is a loophole in the system where a user can keep the sensors active longer than recommended and thus compromise the accuracy of the blood glucose values returned by the glucose monitor.

Moreover, the sensor often absorbs polluting species, such as peptides and small protein molecules during the life of the sensor. Such polluting species can reduce the electrode surface area or diffusion pathway of analytes and/or reaction byproducts, thus reducing the sensor accuracy. Determining when such pollutants are affecting the sensor signal and how to remedy such conditions is quite significant in sensor operation.

The current state of the art in continuous glucose monitoring (CGM) is largely adjunctive, meaning that the readings provided by a CGM device (including, e.g., an implantable or subcutaneous sensor) cannot be used without a reference value in order to make a clinical decision. The reference value, in turn, must be obtained from a finger stick using, e.g., a BG meter. The reference value is needed because there is a limited amount of information that is available from the sensor/sensing component. Specifically, the only pieces of information that are currently provided by the sensing component for processing are the raw sensor value (i.e., the sensor current